Document Title: SOPs: Production, Approval and Review

Document Number: R&D SOP001

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Summary of Amendments

Version Number	Modification:
Version 12	Added process for archiving SOP/GD/Form or Template. Amendment to approval process for forms, template and guidance documents. Clarification re the process for CRF SOPs and documents. Reviewed for changes in regards to the new clinical trial E6 R3 regs.
Version 11.0	Changes to the Quality Management System from OpenClinica to IQM; documents will be acknowledged on IQM rather than wet ink and scanned; change of R&D Clinical Director. Inclusion of change requests in IQM and how they will be processed and actioned once received. Clarification from R&D Manager: The SOPs need to be reviewed by 2 people not necessarily CPMs – a lead reviewer who is the owner on IQM plus a second reviewer. These should be chosen based on expertise.
Version 10.0	Minor procedural changes throughout

Version 9.0	Changes to reflect that OpenClinica is being used instead of paper-training records.
Version 8.0	To amend the process for review of currently approved SOPs – limiting review and implementation of amendments to a lead Clinical Project Manager (CPM) along with two further CPMs acting as reviewers.

Key related documents:	Trust Policy DN001 Document Control Procedures SOP002 Training Records for Research Active Staff SOP050 Handling of Non-Compliance

Key Points of this Document

- This document sets out the procedures to be followed by all Royal Papworth Hospital Staff who are involved in the preparation, review, dissemination and implementation of Standard Operating Procedures (SOPs) for the core activities of clinical research.
- It provides guidance on the steps involved in the preparation of SOPs to ensure compliance with the Trust's policies.

1 Purpose and Contents

a. This document defines the Trust's procedures for preparing, managing and reviewing Standard Operating Procedures (SOPs) that describe the standard activities used in research at Royal Papworth Hospital NHS Foundation Trust and Papworth Trials Unit Collaboration (PTUC).

b. The document details the requirements for written SOPs to provide quality assurance as described in Good Clinical Practice.

c. All core clinical trial activities need to be supported by appropriate SOPs. This document provides guidance on the preparation and review of these departmental and trials unit SOPs so as to comply with the Trust's policies on document preparation and control.

2 Roles & Responsibilities

a. This Policy applies to all personnel that are conducting research at the Trust. Staff involved in the preparation, review and dissemination of SOPs must comply with the requirements set out in section 4.

b. It is the responsibility of all personnel involved in research at the Trust to ensure that they are familiar with and adhere to all current SOPs and have acknowledged on IQM to confirm that the relevant SOPs have been read.

2.1 SOP Committee

a. The R&D Department SOP committee consists of the R&D Managers, Clinical Project Managers, SOP Administrator, Team Leaders, Research Nurse/Clinical Trial Coordinator. Clinical representation from a Consultant Clinician will be sought as and when required depending upon the SOPs being reviewed.

b. The R&D SOP Committee is responsible for identifying the need for a new SOP and arranging its production, review, ratification and implementation. The need for a new SOP may also be identified by other staff within the department and communicated to the SOP committee for action.

c. The SOP Committee, SOP review programme and meeting dates are available from the SOP Administrator. The meeting activities may be completed by remote means (e.g. email, teleconference) when necessary.

d. The committee is responsible for identifying and organising further representation from the specialists/staff groups for the inception/review of an SOP where they may be particularly affected by the implementation of that SOP.

e. The task of preparing the SOP may be delegated to R&D personnel who are deemed to have the appropriate knowledge and experience.

f. The SOP committee is responsible for identifying and arranging provision of any training that the introduction of a new SOP will require for staff to be able to perform their role in compliance with the SOP.

3 Policy

a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with it may result in disciplinary procedures.

4 Procedure

4.1 Writing SOPs

a. A review of the background context, including statutory or regulatory requirements, should be undertaken as part of the development of a new SOP. Stakeholders should be consulted as required including those who will carry out the SOP in practice.

b. Before an SOP is produced, the activity will be mapped to describe the process in a stepwise fashion. This will be used to draft the SOP using the department's standard SOP template

to ensure compliance with the Trust's policy DN001. Updates to the SOP template will be managed by the SOP Administrator and all versions will be stored and can be made available upon request.

c. All SOPs must include a version control history that must be updated with each change to the SOP. All SOPs will have a review date and version number in the footer, and numbered pages in the page x of y format. The preferred numbering system is: version 1.0 (initial approved document); versions 2.0, 3.0 etc (subsequent updated documents which have been approved).

d. Unapproved draft versions for review will be marked with version 1.1, 1.2 etc. The "DRAFT" watermark should be displayed diagonally on the page.

e. New SOPs should be generated in MS Word from the current SOP template. This will be managed by the SOP Administrator.

f. New SOPs will be given the next sequential whole number (SOPXXX) upon upload to IQM. If the title of a published SOP requires amending when preparing a new version, the document will not require a new sequential number.

g. SOPs which are only relevant for studies either sponsored by Royal Papworth Hospital or managed by Papworth Trials Unit Collaboration are named PTUC in the Document Number i.e. PTUC SOPXXX. SOPs which are relevant to all personnel that are conducting research at the Trust including staff that are full or part-time employees of the Trust are named R&D in the Document Number. SOPs which are relevant to the Clinical Research Facility are named HLRI CRF in the Document Title. SOPs for Tissue Bank will have TB_SOPXXX in the Document Number.

h. When uploading new or amended SOPs to IQM the SOP administrator will enter the keyword PTUC or CRF for the relevant SOPs.

i. On completion, the draft SOP will be reviewed internally by the SOP Committee to look at compliance with the regulations, readability and accuracy of information.

j. Any forms, templates or guidance documents that are quoted, enclosed or embedded within the SOP will also be reviewed by the SOP Committee.

k. For each new/revised SOP, the SOP Committee will assess what level of training is required, and in what format it will be delivered. The type and level of training should be appropriate to the roles and responsibilities of specific members of staff and the procedure concerned. Classroom based training may be required when competency sign-off is necessary, where complex processes or concepts are involved, or for staff new to the role or task. Realistic timeframes for the completion of training should be set.

l. All SOPs must include a version control history that must be updated with each change to the SOP. The Summary of Amendments table at the front of the document will be completed to document any changes since the previously ratified SOP.

4.2 Approving SOPs

a. When the SOP committee agrees that the SOP is ready for ratification the SOP administrator must ensure:

1. the SOP is on the correct template;
2. the watermark is removed;
3. the version number updated to the next whole number and planned review date added to the footer and front page of the SOP.

b. SOPS relating to the Heart Lung Research Institute (HLRI) Clinical Research Facility (CRF) will be approved by the HLRI CRF Clinical Director prior to approval by the R&D Clinical Director and R&D Manager.

c. SOPs relating to Pharmacy and R&D will be approved within Pharmacy's management committee and then submitted to the SOP committee for review and approval.

d. SOPs specific to Tissue Bank will be approved within their own management committee and submitted as active documents to be uploaded to IQM. The SOP administrator will inform the Chair of the SOP Committee for information only.

e. The SOP is then submitted by the SOP Administrator to the Clinical Director of Research and Development and R&D manager for approval via IQM.

f. The Approvers will accept or reject the SOP and provide any comments in IQM.

g. Final approval will be provided by the Clinical Director of R&D.

h. Once approved the SOP administrator will activate and distribute the SOP in IQM.

i. All SOPs will have an effective date of four weeks after the SOP is distributed on IQM.

4.3 Authorising documents, forms and templates

a. The SOP administrator will submit forms, templates and guidance documents to the next available SOP Committee meeting for discussion and approval.

b. Once approved, guidance documents, forms and templates will be uploaded, activated, and distributed in IQM.

c. Forms, templates and guidance documents specific to Tissue Bank will be approved within their own management committee and submitted as active documents to be uploaded to IQM. The SOP administrator will inform the Chair of the SOP Committee for information only.

4.4 Activation and Distribution

a. Upon acknowledgement, the SOP Administrator will upload:

1. The PDF of the SOP or guidance document for inclusion on the R&D SOP web pages.
2. The word / excel version of the form or template for inclusion on the R&D web pages.

b. All R&D personnel and study support staff will be made aware of new versions of SOPs via automated reminders from IQM, emails from the SOP administrator and at the monthly departmental staff ('Buzz') meetings,

c. Any existing clinical trial documentation, or departmental written and electronic material that refers in any way to a superseded version of an SOP, should be updated to reflect the new SOP.

d. Staff should acknowledge that they have read and completed any required training relating to the SOP in IQM.

e. SOPs should be read within four weeks of release, and required training completed before the member of staff performs the particular clinical trial activity. Compliance will be monitored by auditing of the IQM records (SOP002 Training Records for Research Active Staff).

f. The impact of new or revised SOPs on ongoing trials will be reviewed by the SOP Committee. All staff acknowledging must review the impact on their studies and report any potential impacts to the SOP committee. Actions to ensure stakeholders are alerted to any potential impact, the actions which may be needed to address these, and training requirements will be identified and minuted.

g. Whilst SOPs may be printed, the electronic version maintained on IQM is the controlled copy. Any printed copies are not controlled.

4.5 Change requests in IQM for SOPs

a. If staff notice something that is not correct in the content of the SOP, they can raise a change request in IQM. The SOP administrator and QA Manager will be notified automatically of any change requests via IQM.

b. If the change request relates to significant changes to the content of the SOP it will go to the next SOP Committee meeting or IQM Working Group meeting for review. If the committee agrees the change is needed a revised version of the SOP will be created and uploaded to IQM for approval.

c. If the change request relates to the formatting of the SOP, it will be accepted in IQM but a comment will be added to include the change in the next review of the SOP.

4.6 Archiving of SOPs

a. When a SOP is no longer required it must be taken to the SOP committee for agreement.

b. Following agreement to archive a SOP (or form, template or guidance document) the QA team will check whether there are any other documents (SOPs/GD/TPL/FRM) that reference the 'to be archived' SOP.

c. The archived SOP will have 'ARCHIVED' added to the folder on the shared drive (S/R&D/SOPs/SOPs) and the document will be made 'obsolete' and archived on IQM.

d. References to the archived document will be removed from any SOPs and a new version of the SOP will be created and forwarded to the Senior R&D Manager for Chair's approval outside the committee meeting. Once approved it will be uploaded to IQM for ratification. This will then be distributed to staff with a note that the only change is the removal of a reference to the archived document.

e. Where the archived document is referenced in a guidance document, form or template it shall be removed and a new version of the relevant document created. It will then be forwarded to the Senior R&D Manager for Chair's approval outside the committee meeting. Once approved it will be uploaded to IQM as the new active version.

4.7 Deviations from SOPs

a. The R&D Department has an open policy to encourage declaration of deviations from SOPs. It is the responsibility of staff to report SOP deviations to the Senior Managers and record these deviations as file notes or non-compliance (SOP050) in the trial master file making clear which version of the SOP is being implemented.

b. All reported deviations will be reviewed by the QA committee and any necessary actions agreed.

4.8 Review of currently approved SOPs

a. SOPs should be reviewed at least every three years to ensure compliance with the Trust's Policy DN001 or if the SOP Committee is alerted to SOPs that need amending before their review date e.g. in response to changes in practice, regulations or legislative requirements.

b. The designated review date of a particular SOP will be detailed on the SOP itself.

c. The SOP Administrator will inform the QA Manager/Committee Chair of any SOP requiring review and the decision will be made who will lead and who will be second reviewer. The Committee agenda will then be confirmed.

d. It will be the responsibility of these identified members, to also ensure any hyperlinks; references; associated forms or templates are also current.

e. Identified members will need to check the change request section of the SOP's 'document details' in IQM to ensure that any change requests are incorporated.

f. Where an SOP requires updating, identified members will make all necessary changes, and submit the SOP to the next SOP committee meeting. Approval will then take place in the same way as detailed in section 4.2.

g. If the SOP does not need updating, the amended SOP will be submitted to the Chair of the SOP committee for final review prior to being submitted to the Clinical Director of R&D for signature.

h. The review date of an amended SOP will be shifted to reflect the date of the latest review.

i. Superseded (approved and implemented) versions of SOPs from December 2023 onward will be archived and retained on IQM by the SOP Administrator, as well as being archived on the shared drive. All previous versions prior to IQM will be archived on the shared drive.

j. Regulatory Changes: For minor wording changes the current version of the SOP will be amended and forwarded to the SOP committee Chair for approval. It does not need to go to a SOP committee meeting for review or approval. The SOP will then be uploaded to IQM, with the same version number, using the 'set index option'. This retains the original document for audit purposes but ensures staff access the updated document. As this document is not treated as a new version and contains minor wording changes it will not be distributed for staff to reread.

4.9 Review of currently approved forms, templates and guidance documents

a. Forms, templates and guidance documents should be reviewed alongside the relevant SOP.

b. Where a form, template or guidance document requires updating, identified members will make all necessary changes, and submit to the next SOP committee meeting for review and approval

c. Once approved the SOP Administrator will upload the documents to IQM and the R&D web pages.

5 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	Current approved version date
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 (and any subsequent amendments). UK Policy Framework for Health and Social Care Research version 3.3 (07/11/17) and authorised amendments thereafter.

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Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative							

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